IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of)
Yukihiro Fujieda, et al.) Examiner : Bruenjes,C.P.
Serial No. :09/926,817)
Filed : December 21, 2001) Group Art Unit: 1772
For: Multi-Layered Tube and
Medical Device comprising
Multi-Layered Tube

DECLARATION UNDER 37 C.F.R.§ 1.132

Honorable Commissioner of Patent and Trademarks
Alexandria Virginia 22323

SIR:

I, HISATOKI YAMAOKA, do hereby solemnly declare and state that:

1. I graduated from Oita University, Faculty of Engineering, in 1999, with a Bachelor of Science degree in production system engineering.

2. I am now, and have been since 1999 an employee of Kawasumi Laboratories, Inc. (the Company), located 7-1, Oaza Tamada, Mie-Cho, Ono-gun, Oita 879-7153 Japan.

3. Since 2001, I have been working at the Research and Development Division, mainly engaged in polymer processing and evaluation of new polymer materials.

4. I have conducted, or have had conducted under my supervision and control the following experiments:

Experiments:

(a) The purpose of the experiments is to prepare several three layered medical tubes conformed to the present invention and hypothetically according to the "teaching of Kodama et al."* and evaluate their properties as medical tubes when subjected to steam sterilization.

The experiments were carried out at Production division of Mie factory of the Company from February 1 to 14, 2005.

(*Note: In this Experiment 2, by "Kodame et al.'s hypothetical tube" is meant a kind of hypothetical or imaginary tube, which was formed on an assumption that if "Kodame et al.'s film-forming random co-polymer materials were to be applied to make a three-layered tube. Since, the Examiner admitted, Kodame et al. is directed to only a multi-layered wrapping film, and is completely silent about any tubes.)

(b) Three-layered tubes, having an outer layer(II')/intermediate layer(I)/inner layer(II), were co-extruded in a co-extrusion device shown in Fig. 1. Preliminarily dry-blended resins (II),(I),and (II') were supplied through hoppers 1, 2, and 3 to extruders 4, 5, and 6 respectively, and melt-kneaded in the extruders at 230℃. Each exit portion of the three extruders was connected to a three-layer-die 7, to which melted resins (II), (I) and (II') were fed under pressure and co-extruded to form a three-layered tube with an inner diameter of 3.7mm and an outer diameter of 6.0mm, with an outer layer and inner layer of 5 μm thick and an

intermediate layer about 1050 μm thick. In Fig.1 is a cooling bath for sizing tube and 9 is an intake roll.

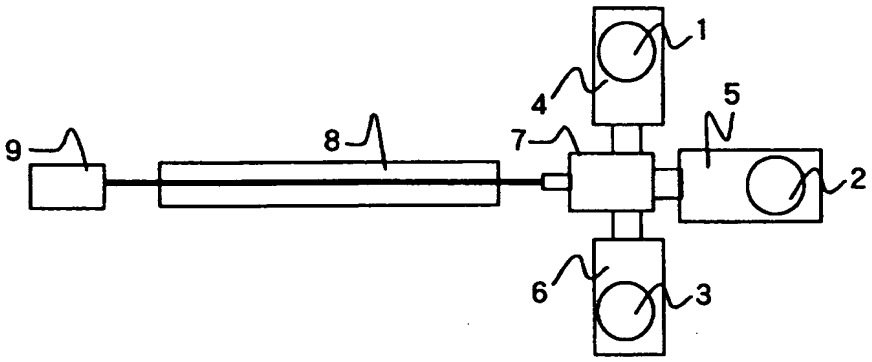

Fig.1

(c) The compositions of the three-layered tube are summarized in Table 1. (In table 1, Experiment 1 is the case wherein tubes are conforming to the scope of the present invention, and Experiment 2 shows those of Kodama et al.'s hypothetical tube.)

Table 1

	Experiment 1	Experiment 2
	Present Invention	Kodama et al. (hypothetical tube)
Connection layer(II') (outer layer)	(a') 50 mass% of a polypropylene resin and (b') 50 mass% of a hydrogenated isoprene block copolymer	(A') 50 mass% of a polypropylene resin and (B') 50 mass% of a hydrogenated styrene-butadiene random copolymer
Substrate layer(I) (intermediate layer)	(a) 30 mass% of a polypropylene resin and (b) 70 mass% of a hydrogenated isoprene block copolymer	(A) 30 mass % of a polypropylene resin and (B) 70 mass %of a hydrogenated styrene-butadiene random copolymer
Connection layer(II) (inner layer)	(a') 100 mass% of a polypropylene resin	(A') 100 mass% of a polypropylene resin

(NOTE)
1) In the Experiment 1, as hydrogenated isoprene block copolymer, used Hybrar HVS-3(trade name) supplied by Kraray Ltd.
2)In the Expriment 2, as hydrogenated styrene-butadiene random copolymer, used DYNARON 1320P(trade name) supplied by JSR.
3) In the Experiments 1-2, as polypropylene resin, used F327(trade name)supplied by Grand Polymer Co..

(d) Three-layered tubes thus obtained were evaluated for (i) Anti-kinking properties of tube,(ii) Resistance against tube/tube sticking under heat and (iii) Resistance against tube/film sticking under heat.

(i)(Anti-kinking properties of tube)

A three layered tube having a length of 20 cm was bent in the form of a U-letter and left as it was for approximately 1 minute, and then the tube was observed for a kinking. The tube was measured for a radius of curvature with an R gage, and a smallest radius of curvature at which no kinking occurred was used as an index for anti-kinking properties. Ten tube samples were measured and the averaged value was given in Table 2.
(Evaluation: maximum radius of tube at which kinking occurred; ○: less than 20 mm, ×: 20 mm or more)

(ii) (Resistance against tube/tube sticking under heat)(Tube/tube sticking)

Two three-layered tubes having a length of 10 cm each were stacked such that 5 cm each of them were stacked one on the other in parallel, and the stacked portions were bound with a paper tape. The tubes were subjected to autoclave sterilization (121℃, 20 minutes), and the binding paper tape was removed. The tubes were measured using a tensile tester (Strograph E-L, manufactured by Toyo Seiki Seisaku-sho Ltd.), for a shear peel strength, and the tube/tube sticking strength was used as an index for resistance against sticking under heat. As a shear peel strength, a maximum value obtained under conditions of a test speed of 100 mm/minute with the tensile tester was employed. Ten tube samples were measured and the averaged value was given in Table 2.
(Evaluation: shear peel strength ; ◎: less than 35 N, ○: 35 - 40 N, ×: over 40 N)

(iii) (Resistance against tube/film sticking under heat)(Tube/film sticking)

A three-layered tube having a length of 10 cm was placed in a sterilization bag (supplied by Hogy Medical Co.) and subjected to autoclave sterilization (121℃, 20 minutes). Then, the film was measured, using a tensile tester (Strograph E-L, manufactured by Toyo Seiki Seisaku-sho Ltd.), for a 180° peel strength, and the tube/film sticking was used as an index for resistance against sticking under heat. As a shear peel strength, an average value obtained under conditions of a test speed of

100 mm/minute with the tensile tester was employed. Ten tube samples were measured and the averaged value was given in Table 2.
(Evaluation: 180° peel strength; ○: less than 10 N, ×: 10 N or more)

(e) The results of the evaluation of tubes are summarized in Table 2.

Table 2

	Experiment 1	Experiment 2
	This Invention	Kodama et al.
Anti Kinking property (mm)	14.0<20mm ○	13.0<20mm ○
Tube/tube sticking (N)	34.6<35N ◎	41.3>40N ×
Tube/film sticking (N)	0.25<10N ○	0.25<10N ○

According to the results shown in Table 2, it was found:
The most remarkable difference between Experiment 1(this invention) and Experiment 2 (Kodama et al.) was in Tube/tube sticking, wherein the Tube/tube sticking of the tube of the present invention (34.6N) is less than 35 N (lowest criteria value) and evaluated as very good (◎) , while the value for Kodama et al.'s hypothetical tube (41.3N) was more than 40N and rated as poor (×) , indicating that the tube of the Experiment 2 (Kodama et al.'s hypothetical tube) was not usable as a medical tube because of its poor resistance against tube/tube sticking under heat of sterilization (121℃, 20 minutes). The other two properties (Anti Kinking and Tube/film sticking) were both rated substantially the same (○) with Experiments 1 and 2.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Signed at Oita, Japan This 29 day of March, 2005

Hisatoki Yamaoka
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